

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., et
al.,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA)
Inc. and ZYDUS LIFESCIENCES
LIMITED,

Defendants.

Case No.: 1:24-cv-9512-ESK-AMD

SALIX PHARMACEUTICALS, INC., et
al.,

Plaintiffs,

v.

NORWICH PHARMACEUTICALS, INC.,
ALVOGEN PB RESEARCH &
DEVELOPMENT, LLC, and ALVOGEN,
INC.,

Defendants

Case No.: 1:24-cv-7140-ESK-AMD

~~SALIX PHARMACEUTICALS, INC.,~~
~~SALIX PHARMACEUTICALS, LTD.,~~
~~ALFASIGMA S.P.A. and BAUSCH~~
~~HEALTH IRELAND LTD.,~~
SALIX PHARMACEUTICALS, INC., et
al.,

Plaintiffs,

v.

~~AMNEAL PHARMACEUTICALS OF NEW~~
~~YORK, LLC, and AMNEAL EU,~~
CIPLA
USA, INC. and CIPLA LIMITED,

Defendants.

Case No.: 1:24-cv-~~04607~~-10213-ESK-
AMD

SALIX PHARMACEUTICALS, INC., et
al.,

<u>Plaintiffs,</u>	<u>Case No.: 1:24-cv-10356-ESK-AMD</u>
<u>v.</u>	
<u>CARNEGIE PHARMACEUTICALS LLC,</u>	
<u>Defendant.</u>	

STIPULATED DISCOVERY CONFIDENTIALITY ORDER

WHEREAS the above-captioned matters involving defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (together, “Zydus”), defendants Norwich Pharmaceuticals, Inc., Alvogen PB Research & Development, LLC, and Alvogen, Inc. (together “Norwich”), defendants Cipla USA, Inc. and Cipla Limited (together, “Cipla”), and Carnegie Pharmaceuticals LLC (“Carnegie) are consolidated for discovery purposes along with *Salix Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals of New York LLC and Amneal EU, Limited, et al.*, Civil No. 24-4607, where Amneal Pharmaceuticals of New York LLC and Amneal EU, Limited (together, “Amneal”) are defendants (each of Zydus, Norwich Cipla, Carnegie, and Amneal, a “Defendant Group”);

It appearing that discovery in the above-captioned ~~action~~actions is likely to involve the disclosure of confidential information, it is ORDERED as follows:

1. Any party to this litigation and any non-party providing information in this action (hereinafter “non-party”) shall have the right to designate as “Confidential” and subject to this Order any information, document, or thing, or portion of any document or thing: (a) that contains trade secrets, competitively sensitive technical, marketing, financial, sales or other confidential business information, or (b) that contains private or confidential personal information, or (c) that contains information received in confidence from third parties, or (d) which the producing party otherwise believes in good faith to be entitled to protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure and Local Civil Rule 5.3. Any party to this litigation or non-party covered by this

Order, who produces or discloses any Confidential material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: “CONFIDENTIAL” or “CONFIDENTIAL –

SUBJECT TO CONFIDENTIALITY ORDER” (hereinafter “Confidential”). All documents, copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such confidential information shall also be deemed “CONFIDENTIAL.” Each party shall act in good faith in designating information as “CONFIDENTIAL.”

- a. For the avoidance of doubt, any Abbreviated New Drug Application (“ANDA”), New Drug Application (“NDA”), Drug Master File (“DMF”), any internal correspondence about or correspondence with FDA, or filings related to said ANDA, NDA, or DMF, and other technical information (including information regarding the research and development of the patents-in-suit and the research and development of ~~Defendants’~~ Defendant’s ANDA product) shall be designated “CONFIDENTIAL.”

2. Any party to this litigation and any non-party shall have the right to designate as “Attorneys’ Eyes Only” and subject to this Order any information, document, or thing, or portion of any document or thing that contains highly sensitive business or personal information, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the designating party. Any party to this litigation or any non-party who is covered by this Order, who produces or discloses any Attorneys’ Eyes Only material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: “ATTORNEYS’ EYES ONLY” or “ATTORNEYS’ EYES ONLY – SUBJECT TO CONFIDENTIALITY ORDER”

(hereinafter “Attorneys’ Eyes Only”). All documents, copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such Attorneys’ Eyes Only information shall also be deemed “ATTORNEYS’ EYES ONLY.” Each party shall act in good faith in designating information as “ATTORNEYS’ EYES ONLY.”

3. Also, for the avoidance of doubt, information and things derived from Confidential and/or Attorneys' Eyes Only material, including summaries, digests, analyses, and other records of such information and things, and any testing or test results of product samples shall be subject to the same Confidential and/or Attorneys' Eyes Only designation (and thus the same restrictions) as the information or thing from which it was derived. All Confidential and/or Attorneys' Eyes Only material shall be securely maintained by recipients so as to preclude access by persons who are not entitled to receive such Confidential and/or Attorneys' Eyes Only materials.

4. All Confidential and Attorneys' Eyes Only material shall be used by the receiving party solely for purposes of the prosecution or defense of this action, shall not be used by the receiving party for any business, commercial, competitive, personal or other purpose, and shall not be disclosed by the receiving party to anyone other than those set forth in Paragraph 6 with respect to Confidential material, or set forth in Paragraph 8 with respect to Attorneys' Eyes Only material, unless and until the restrictions herein are removed either by written agreement of counsel for the parties, or by Order of the Court. It is, however, understood that counsel for a party may give advice and opinions to his or her client solely relating to the above-captioned action based on his or her evaluation of Confidential and/or Attorneys' Eyes Only material, provided that such advice and opinions shall not reveal the content of such Confidential and/or Attorneys' Eyes Only material except by prior written agreement of counsel for the parties, or by Order of the Court. All Confidential and Attorneys' Eyes Only material produced by any Defendant Group to Plaintiffs shall not be disclosed by Plaintiffs to any other Defendant Group without prior written consent of such producing Defendant Group, except that Plaintiffs may serve expert reports containing the confidential information of more than one Defendant Group as long as such expert report and materials cited therein are restricted to outside counsel only.

5. Absent consent of the producing party and/or further Order of this Court, all persons receiving information designated Confidential or Attorneys' Eyes Only material under this

Discovery Confidentiality Order concerning polymorphic forms of rifaximin or methods of treatment using rifaximin (550 mg) from an opposing party in this action are expressly prohibited during the pendency of this action and for one year thereafter

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from ~~using or disclosing such information: (i) while~~(i) drafting, amending, or providing instruction with respect to drafting or amending claims of patents or patent applications before the United States Patent and Trademark Office (“PTO”) ~~concerning~~or any foreign patent office encompassing rifaximin (550 mg); and (ii) using or disclosing such information in connection with communications with the United States Food and Drug Administration (“FDA”), including, but not limited to, in connection with Citizens Petitions. Notwithstanding the foregoing, nothing herein shall preclude persons receiving information designated Confidential or Attorneys’ Eyes Only from an opposing party in this action from working on and participating in, directly or indirectly, (i) all aspects of any *inter partes* review, post-grant review, or re-issue or ~~re-examination~~re-examination proceeding at the PTO or the Patent Trial and Appeal Board (“PTAB”) ~~concerning~~encompassing rifaximin (550 mg) and (ii) all aspects of any pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court for a patent or patent application ~~concerning~~encompassing rifaximin (550 mg), so long as such work does not include ~~substantive~~ involvement in amendments ~~broadening the scope~~ of patent claims ~~concerning~~encompassing rifaximin (550 mg) or the addition of new claims ~~concerning~~encompassing rifaximin (550 mg) ~~broader in any respect from the broadest of the existing claims~~. For clarity, the foregoing restrictions shall apply only to individuals, and not to the firms or organizations by which they are employed. Additionally, nothing in this paragraph shall preclude any person from providing legal advice concerning this litigation. Moreover, notwithstanding the above, the designated in-house attorneys/personnel of the receiving party shall not be prohibited from advising and representing the receiving party in communications with FDA or the Federal Trade Commission related to the ~~above referenced~~approval or maintenance of approval of the receiving party’s own ANDA or NDA for rifaximin (550 mg).

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6. Confidential material and the contents of Confidential material may be disclosed only to the following individuals under the following conditions:

- a. Outside counsel of record (herein defined as any attorney at the parties' outside law firms, which firms have appeared in the action) and their partners, counsel, associates, paralegals, secretaries, and employees to whom it is reasonably necessary to disclose the information for this litigation, provided outside counsel undertakes to ensure compliance with this Order by anyone in its employ, whether temporary or permanent;
- b. When Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., or Bausch Health Ireland Ltd. (collectively, "Bausch") is the receiving party, up to three (3) in-house attorneys¹ employed by Bausch and their respective secretarial, clerical, and paralegal personnel, provided that such in-house attorneys: (i) are required to participate in decisions with reference to this lawsuit or are persons necessary for the prosecution or defense of this lawsuit and (ii) prior to any designated in-house attorney for Bausch receiving "CONFIDENTIAL" information, Bausch must serve on all producing parties a completed and signed undertaking in the form of Exhibit A attached hereto from such in-house attorney, but a curriculum vitae is not required;
- c. When Alfasigma S.p.A. ("Alfasigma") is the receiving party, up to three (3) in-house attorneys employed by Alfasigma and their respective

¹ Parties can designate in-house intellectual-property personnel who are responsible for supervising the above-captioned action in place of any of the permissible number of in-house attorneys. This footnote applies to any use of "in-house attorney(s)" in this order.

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secretarial, clerical, and paralegal personnel, provided that such in-house attorneys: (i) are required to participate in decisions with reference to this lawsuit or are persons necessary for the prosecution or defense of this lawsuit and (ii) prior to any designated in-house attorney for Alfasigma receiving

“CONFIDENTIAL” information, Alfasigma must serve on all producing parties a completed and signed undertaking in the form of Exhibit A attached hereto from such in-house attorney, but a curriculum vitae is not required;

- d. When ~~Amneal~~Carnegie Pharmaceuticals ~~of New York, LLC~~ or ~~Amneal EU, Carnegie Pharma~~ Limited (collectively, “~~Amneal~~Carnegie”) is the receiving party, up to three (3) in-house attorneys/personnel employed by ~~Amneal~~Carnegie and their respective secretarial, clerical, and paralegal personnel, provided that such in-house attorneys/personnel: (i) are required to participate in decisions with reference to this lawsuit or are persons necessary for the prosecution or defense of this lawsuit and (ii) prior to any designated in-house attorney/personnel for ~~Amneal~~Carnegie receiving “CONFIDENTIAL” information, ~~Amneal~~Carnegie must serve on all producing parties a completed and signed undertaking in the form of Exhibit A attached hereto from such ~~in-house~~in-house attorney/personnel, but a curriculum vitae is not required;

- e. When Zydus is the receiving party, up to three (3) in-house attorneys/personnel employed by Zydus and their respective secretarial, clerical, and paralegal personnel, provided that such in-

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house attorneys/personnel: (i) are required to participate in decisions with reference to this lawsuit or are persons necessary for the prosecution or defense of this lawsuit and (ii) prior to any designated in-house attorney/personnel for Zydus receiving “CONFIDENTIAL” information, Zydus must serve on all producing parties a completed and signed undertaking in the form of Exhibit A attached hereto from such in-house attorney/personnel, but a curriculum vitae is not required;

f. When Cipla is the receiving party, up to three (3) in-house attorneys/personnel employed by Cipla and their respective secretarial, clerical, and paralegal personnel, provided that such in-house attorneys/personnel: (i) are required to participate in decisions with reference to this lawsuit or are persons necessary for the prosecution or defense of this lawsuit and (ii) prior to any designated in-house attorney/personnel for Cipla receiving “CONFIDENTIAL” information, Cipla must serve on all producing parties a completed and signed undertaking in the form of Exhibit A attached hereto from such in-house attorney/personnel, but a curriculum vitae is not required;

g. When Norwich is the receiving party, up to three (3) in-house attorneys/personnel employed by Norwich and their respective secretarial, clerical, and paralegal personnel, provided that such in-house attorneys/personnel: (i) are required to participate in decisions with reference to this lawsuit or are persons necessary for the

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prosecution or defense of this lawsuit and (ii) prior to any designated in-house attorney/personnel for Norwich receiving “CONFIDENTIAL” information, Norwich must serve on all producing parties a completed and signed undertaking in the form of Exhibit A attached hereto from such in-house attorney/personnel, but a curriculum vitae is not required;

h. ~~e.~~ Outside experts or consultants, and their staff to whom disclosure is reasonably necessary for this litigation, retained by outside counsel for purposes of this action, whether as a consulting or testifying expert. Before an expert may receive “CONFIDENTIAL” information, the party retaining the expert must serve on all other parties a completed and signed undertaking in the form of Exhibit A attached hereto from such expert. Counsel who retained the expert shall forward a copy of the executed undertaking to counsel for the producing party at least five (5) business days prior to the proposed disclosure of “CONFIDENTIAL” information to such

expert, along with a copy of that expert’s up-to-date resume or curriculum vitae setting forth his or her name, address, qualifications, and work experience including: (i) the identification of any consulting or other relationship to the parties in this litigation within the last five (5) years (excluding disclosure of the details of any non-testifying litigation consulting, but including disclosure of the identification of the entities for which consulting was provided); and (ii) any deposition or trial testimony given within the last four (4) years. If the producing party objects in writing to the proposed disclosure within five (5) business

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days after receipt of notice, the disclosure may not be made without separate agreement by the parties or prior approval by the Court. If the issue requires Court involvement, the burden shall be on the objecting producing party to present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.1(a), within five (5) business days after receipt of the notice showing the Court why the disclosure should not be made. “CONFIDENTIAL” information may be disclosed to the independent experts and their staff retained to assist the parties in the conduct of this Action after the time allowing for filing the dispute with the Court has passed;

i. ~~f.~~ Secretarial, paralegal, clerical, duplicating and data processing personnel of the foregoing;

j. ~~g.~~ The Court and court personnel and official Court reporters to the extent that “CONFIDENTIAL” information is disclosed at a deposition or court session in which such reporter is transcribing;

k. ~~h.~~ Any deponent may be shown or examined on any information, document or thing designated “CONFIDENTIAL” if it appears that the witness authored or received a copy of it, was (or is currently) employed by the party who produced the information, document or thing, is designated by the producing party under Fed. R. Civ. P. 30(b)(6) to provide testimony on a topic relevant to the Confidential material, or if the producing party consents to such disclosure;

l. ~~i.~~ Vendors retained by or for the parties to assist in preparing for pretrial discovery, trial and/or hearings including, but not limited to, court reporters, litigation support personnel, jury consultants, individuals to prepare

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demonstrative and audiovisual aids for use in the courtroom or in depositions or mock jury sessions, as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials;

m. ~~j.~~ Any mediators engaged by the parties, and their support staff;

n. ~~k.~~ The author or recipient of the Confidential information (not including a person who received the document in the course of the litigation); or other individual who had authorized access to the Confidential information; and

o. ~~l.~~ Any other person: (i) agreed to in writing by the parties, as long as such person signs the undertaking in the form of Exhibit A, or are (ii) permitted by the Court.

7. Confidential material, copies thereof, and the information contained therein, shall not be disclosed in any manner to any other individual, until and unless (a) outside counsel for the party asserting confidentiality waives the claim of confidentiality, or (b) the Court orders such disclosure.

8. Attorneys' Eyes Only material and the contents of Attorneys' Eyes Only material may be disclosed only to the following individuals under the following conditions:

- a. Outside counsel of record (herein defined as any attorney at the parties' outside law firms, which firms have appeared in the action) and their partners, counsel, associates, paralegals, secretaries, and employees to whom it is reasonably necessary to disclose the information for this litigation, provided outside counsel undertakes to ensure compliance with this Order by anyone in its employ, whether temporary or permanent;

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b. - One (1) in-house attorney from Plaintiffs and one (1) in-house attorney or personnel from ~~Defendants~~ each Defendant and their respective secretarial, clerical, and paralegal personnel, provided that such in-house attorneys: (i) are required to participate in decisions with reference to this lawsuit or are persons necessary for the prosecution or defense of this lawsuit and (ii) prior to any designated in-house attorney receiving “ATTORNEYS’ EYES ONLY” information, all producing parties must be served a completed and signed undertaking in the form of Exhibit A attached hereto from such in-house attorney, but a curriculum vitae is not required;

c. Outside experts or consultants, and their staff to whom disclosure is reasonably necessary for this litigation, retained by outside counsel for purposes of this action, whether as a consulting or testifying expert. Before an expert may receive " ATTORNEYS’ EYES ONLY” information, the party retaining the expert must serve on all other parties a completed and signed undertaking in the form of Exhibit A attached hereto from such expert. Counsel who retained the expert shall forward a copy of the executed undertaking to counsel for the producing party at least five (5) business days prior to the proposed disclosure of “ATTORNEYS’ EYES ONLY” information to such expert, along with a copy of that expert’s up-to-date resume or curriculum vitae setting forth his or her name, address, qualifications, and work experience including: (i) the identification of any consulting or other relationship to the parties

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in this litigation within the last five (5) years (excluding disclosure of the details of any non-testifying litigation consulting, but including disclosure of the identification of the entities for which consulting was provided); and (ii) any deposition or trial testimony given within the last four (4) years. If the producing party objects in writing to the proposed disclosure within five (5) business days after receipt of notice, the disclosure may not be made without separate agreement by the parties or prior approval by the Court. If the issue requires Court involvement, the burden shall be on the objecting producing party to

present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.1(a), within five (5) business days after receipt of the notice showing the Court why the disclosure should not be made. “ATTORNEYS’ EYES ONLY” information may be disclosed to the independent experts and their staff retained to assist the parties in the conduct of this Action after the time allowing for filing the dispute with the Court has passed;

- d. Secretarial, paralegal, clerical, duplicating and data processing personnel of the foregoing;
- e. The Court and court personnel and official Court reporters to the extent that “ATTORNEYS’ EYES ONLY” information is disclosed at a deposition or court session in which such reporter is transcribing;
- f. Any deponent may be shown or examined on any information, document or thing designated “ATTORNEYS’ EYES ONLY” if it appears that the witness authored or received a copy of it, , was (or is currently) employed

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by the party who produced the information, document or thing, is designated by the producing party under Fed. R. Civ. P. 30(b)(6) to provide testimony on a topic relevant to the Attorneys' Eyes Only material, or if the producing party consents to such disclosure;

g. Vendors retained by or for the parties to assist in preparing for pretrial discovery, trial and/or hearings including, but not limited to, court reporters, litigation support personnel, jury consultants, individuals to prepare demonstrative and audiovisual aids for use in the courtroom or in depositions or mock jury sessions, as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials; and

h. Any mediators engaged by the parties, and their support staff;

i. The author or recipient of the Attorneys' Eyes Only information (not including a person who received the document in the course of the litigation); or other individual who had authorized access to the Attorneys'

Eyes Only information; and

j. Any other person: (i) agreed to in writing by the parties, as long as such person signs the undertaking in the form of Exhibit A, or (ii) permitted by the Court.

9. Attorneys' Eyes Only material, copies thereof, and the information contained therein, shall not be disclosed in any manner to any other individual, until and unless (a) outside counsel for the party asserting confidentiality waives the claim of confidentiality, or (b) the Court orders such disclosure.

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10. Redacted Copies of Confidential and/or Attorneys' Eyes Only Documents for Disclosure to In-House Attorneys/Personnel.

- a. Court Filings and Served Documents: With respect to any document filed or served by any party that is designated as Confidential and/or Attorneys' Eyes Only or contains information designated as Confidential and/or Attorneys' Eyes Only, the filing or serving party shall state to the other party within three (3) business days of the filing or service date, unless otherwise agreed by the parties, if the document contains only the other party's

Confidential and/or Attorneys' Eyes Only material (i.e., does not contain the filing or serving party's Confidential and/or Attorneys' Eyes Only material) such that the document may be disclosed to the other party's ~~in-house~~in-house attorneys/personnel.

- b. Redacted Copies of Court Filings and Served Documents. With respect to any document filed or served by any party that is designated as Confidential and/or Attorneys' Eyes Only or that contains information designated as Confidential and/or Attorneys' Eyes Only with such Confidential and/or Attorneys' Eyes Only information including the filing or serving party's Confidential and/or Attorneys' Eyes Only material, unless otherwise agreed by the parties, the producing party shall, within five (5) business days of filing or service, provide the receiving party with a redacted, non-public version in which the filing or service party's own Confidential and/or Attorneys' Eyes Only material is redacted so that the document may be shared with the in-house attorneys/personnel of the receiving party.

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- c. For Paragraph 10.b, the parties shall not be required to provide redacted versions of Confidential and/or Attorneys' Eyes Only exhibits to briefs, letters, declarations or expert reports; however, each party reserves the right to request redacted copies of said exhibits on a case-by-case basis.
- d. For the avoidance of doubt, the redacted copies provided in Paragraph 10.b are non-public copies.

11. Nothing in this Order shall preclude a party from disclosing to anyone or using in any way its own Confidential or Attorneys' Eyes Only information and things.

12. The producing party may redact from produced documents, materials, and other things, the following items, or any other item(s) protected from disclosure by statute or decisional authority or agreed upon by the parties or ordered by the Court:

- a. Nonresponsive information, including, but not limited to, proprietary financial material and products unrelated to this action, as well as any other material that is neither relevant to the subject matter of this action nor within the scope of discovery set forth in the Federal Rules of Civil Procedure, provided, however, that such redactions of nonresponsive information is strictly limited to only nonresponsive information and that it does not render the underlying document illegible, unusable, or modify and/or alter the document;
- b. The names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as protected material, regardless of whether the document containing such

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names is designated as protected material pursuant to 21 C.F.R. §§ 314.430(e) and (f) and 20.63(f);

- c. Privileged information (e.g., attorney-client privilege, work product, or any other lawful privilege), which is to be clearly marked as “Privileged”; and
- d. To the extent required by the data privacy laws of the European Union or Italy, a party or third-party may redact information that directly or indirectly identifies, or could be used to identify a person residing in the European Economic Area (“EEA”), including but not limited to identification numbers, first and last names, titles, positions, salary and compensation,

telephone and electronic records, employment history, contact information, personal life data, professional life data, business transaction data, physical data, physiological data, mental data, economic data, cultural data, and social identity data. Before production, a party or third-party may, to the extent required by the data privacy laws of the European Union or Italy, redact from all documents, electronic communications, business transaction data, personal electronic files, personally identifiable information for persons residing in the EEA, and personal information.

- e. Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of a party’s ability to challenge such redactions pursuant to the procedures set forth in this Order. The burden as to the propriety of any redaction remains on the producing party at all times.

13. With respect to any depositions that involve a disclosure of Confidential material or Attorneys’ Eyes Only material of a party or non-party, such party or non-party shall designate

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the transcript as containing Confidential material or Attorneys' Eyes Only material, or both, during the deposition. Alternatively, a producing party may designate testimony or information disclosed at a deposition as "CONFIDENTIAL" or "ATTORNEYS' EYES ONLY" by notifying all parties, in writing, within fifteen (15) days after receipt of the final deposition transcript, which period may be extended by agreement of the parties. If no designation is made at the time of a deposition, that deposition shall be treated as "ATTORNEYS' EYES ONLY" for fifteen (15) days after receipt of the final deposition transcript unless otherwise designated by the above notice. No such deposition transcript shall be disclosed to any individual other than the individuals described in Paragraph 8 for "ATTORNEYS' EYES ONLY" material, and the deponent during these fifteen (15) days, and no

individual attending such a deposition shall disclose the contents of the deposition to any individual other than those described in Paragraph 8 for "ATTORNEYS' EYES ONLY" material, during said fifteen (15) days. Upon being informed that certain portions of a deposition are to be designated as Confidential, or Attorneys' Eyes Only, all parties shall immediately cause each copy of the transcript in its custody or control to be appropriately marked and limit disclosure of that transcript in accordance with this Order.

14. Nothing in this Order shall prejudice the right of any party to bring before this Court, pursuant to L. Civ. R. 5.3(b)(5), any dispute concerning the designation of information as Confidential or Attorneys' Eyes Only. A Party shall not be obligated to challenge the propriety of any designation of Confidential or Attorneys' Eyes Only information or thing at the time the designation is made and failure to do so shall not preclude a subsequent challenge to the designation. If counsel for a party receiving documents or information designated as Confidential

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or Attorneys' Eyes Only hereunder objects to such designation of any or all of such items, the following procedure shall apply:

- a. Counsel for the objecting party shall serve on the designating party or ~~non-party~~nonparty a written objection to such designation, which shall describe with particularity the documents or information in question and shall state the grounds for objection. Counsel for the designating party or non-party shall respond in writing to such objection within seven (7) days, and shall state with particularity the grounds for asserting that the document or information is Confidential or Attorneys' Eyes Only. If no timely written response is made to the objection, the challenged designation will be deemed to be void. If the designating party or nonparty makes a timely response to such objection asserting the propriety of the designation, counsel shall then confer in good faith within seven (7) days of receipt of the designating party's response in an effort to resolve the dispute.
- b. If a dispute as to a Confidential or Attorneys' Eyes Only designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall, within five (5) business days after the meet and confer, present the dispute to the Court in accordance with Local Civil Rule 37.1(a)(1). The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute.

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15. Any document designated “Confidential” or “Attorneys’ Eyes Only” by a party or non-party and which is to be filed with the Court shall be filed under seal, in accordance with Local Civil Rule 5.3.

16. If the need arises during trial or at any hearing before the Court for any party to disclose Confidential or Attorneys’ Eyes Only material, the parties shall meet and confer regarding the procedures for use of Confidential or Attorneys’ Eyes Only material at trial or any evidentiary hearing and shall move the Court for entry of an appropriate sealing order. At trial or evidentiary hearings, the Court may take such other measures or enter separate orders, as the Court deems appropriate or upon request by any party, to protect the designated protected material sought to be introduced or admitted.

17. Data Breach. If a party learns that material that party received in discovery pursuant to this Confidentiality Order has been the subject of a data breach, that party must promptly notify the producing party of the breach, and cooperate with that party to address the breach.

18. The inadvertent or unintentional disclosure of Confidential or Attorneys’ Eyes Only material that should have been designated as such, regardless of whether the information, document or thing was so designated at the time of disclosure, shall not be deemed a waiver in whole or in part of a party’s or non-party’s claim that it is Confidential or Attorneys’ Eyes Only material, either as to the specific information, document or thing disclosed or as to any other material or information concerning the same or related subject matter. Such inadvertent or unintentional disclosure may be rectified by notifying in writing counsel for all parties to whom the material was disclosed that the material should have been designated Confidential or Attorneys’ Eyes Only within a reasonable time from discovery of the error. Such notice shall constitute a designation of the information, document or thing as Confidential or Attorneys’ Eyes

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Only under this Confidentiality Order. No party shall be held in breach of this Discovery Confidentiality Order if, prior to notification of such later designation, such Confidential or Attorneys' Eyes Only material had been disclosed or used in a manner inconsistent with such later designation.

19. The production of any information, document, or thing in this litigation shall not constitute a waiver of any attorney-client privilege or work-product protection that may be asserted by the producing party either in this case or in any other federal or state proceeding. This Order shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence

502(d). A party who inadvertently produces information to which it claims a privilege or immunity may give notice of the inadvertent production to the receiving parties, identifying, preferably by production number, the inadvertently produced information. Upon receipt of the notice and in no event later than ten (10) business days following receipt thereof, the receiving parties shall return or certify destruction of all copies of the inadvertently produced information in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). Additionally, the receiving parties shall destroy all notes, summaries, and compilations in their possession at the time of the notice of inadvertent production that refer to or reproduce, in whole or in part, the inadvertently produced information. That treatment shall be deemed to comply with any obligations the producing party would otherwise have had pursuant to Fed. R. Evid. 502(b) or under the common law. However, nothing herein restricts the right of the receiving party to challenge the producing party's claim of attorney-client privilege or work-product protection pursuant to Fed. R. Civ. P. 26(b)(5)(B).

20. If a non-party serves a party in this action with a request, subpoena, or order ("demand") for disclosure of Confidential or Attorneys' Eyes Only material, the party receiving

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the demand, if not prohibited under applicable law, shall promptly deliver a copy of the demand to the designating party's counsel, and shall notify the party who served the request that some or all of the materials sought by the request are subject to this Confidentiality Order. The party receiving the demand shall not disclose any Confidential or Attorneys' Eyes Only material prior to the date specified for disclosure, or prior to resolution of any dispute regarding production of such material in response to the request, whichever is later. In its sole discretion and at its own cost, the designating party may oppose or seek to limit the demand in any legal manner. The party who received the demand shall not oppose or otherwise interfere with the designating party's actions.

21. No information that is in the public domain or which is already known by the receiving party through proper means or which is or becomes available to a party from a source other than the party asserting confidentiality, rightfully in possession of such information on a ~~non-confidential~~non-confidential basis, shall be deemed or considered to be Confidential or Attorneys' Eyes Only material under this Confidentiality Order.

22. This Confidentiality Order shall not deprive any party of its right to object to discovery by any other party or on any otherwise permitted ground. This Confidentiality Order is being entered without prejudice to the right of any party to move the Court for modification or for relief from any of its terms.

23. This Confidentiality Order shall survive the termination of this action and shall remain in full force and effect unless modified by an Order of this Court or by the written stipulation of the parties filed with the Court.

24. Upon final conclusion of this litigation, including all appeals, each party and each individual subject to the terms hereof shall return or certify destruction of all originals and copies

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of documents and things containing Confidential or Attorneys' Eyes Only information of another party within 120 days after the termination of the action; provided, however, that outside counsel and in-house counsel designated to receive Confidential information and designated to receive Attorneys' Eyes Only information under paragraphs 6 and 8 may retain for archival purposes a complete copy of all pleadings, communications, deposition and hearing transcripts, submissions to the Court, including exhibits submitted therewith, and written discovery, as well as any notes, summaries, or other work files prepared by attorneys/personnel or outside experts or consultants derived from or containing Confidential or Attorneys' Eyes Only information, subject to the provisions of this Order. To the extent a party requests the return of Confidential or Attorneys' Eyes Only material from the Court after the final conclusion of the litigation, including the exhaustion of all appeals therefrom and all related proceedings, the party shall file a motion seeking such relief.

25. The terms of this Discovery Confidentiality Order shall supersede and replace the terms, procedures, restrictions, or obligations agreed to in any Offer of Confidential Access executed by the parties prior to the filing of the above-captioned cases. Any documents or

information produced pursuant to any such Offers of Confidential Access or Local Rule 26.1 shall be treated pursuant to the terms of this Discovery Confidentiality Order.

IT IS SO ORDERED.

Dated: _____

~~Dated:~~ _____

Honorable Anne Marie Donio

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EXHIBIT A

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

<u>SALIX PHARMACEUTICALS, INC., et al.,</u> <u>Plaintiffs,</u> <u>v.</u> <u>ZYDUS PHARMACEUTICALS (USA) Inc. and ZYDUS LIFESCIENCES LIMITED,</u> <u>Defendants.</u>	<u>Case No.: 1:24- cv-9512-ESK-AMD</u>
<u>SALIX PHARMACEUTICALS, INC., et al.,</u> <u>Plaintiffs,</u> <u>v.</u> <u>NORWICH PHARMACEUTICALS, INC., ALVOGEN PB RESEARCH & DEVELOPMENT, LLC, and ALVOGEN, INC.,</u> <u>Defendants</u>	<u>Case No.: 1:24-cv- 7140-ESK-AMD</u>
SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD., <u>SALIX PHARMACEUTICALS, INC., et al.,</u>	Case No.: 1:24- cv- 04607 - <u>10213</u> -ESK- AMD

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<p>Plaintiffs, v.</p> <p>AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and AMNEAL EU, CIPLA USA, INC. and CIPLA LIMITED,</p> <p>Defendants.</p>	<p>AGREEMENT TO BE BOUND BY CONFIDENTIALITY ORDER</p>	
<p><u>SALIX PHARMACEUTICALS, INC., et al.,</u></p> <p><u>Plaintiffs,</u> <u>v.,</u></p> <p><u>CARNEGIE PHARMACEUTICALS LLC,</u></p> <p><u>Defendant.</u></p>	<p><u>Case No.: 1:24- cv-10356-ESK-AMD</u></p>	
<p><u>SALIX PHARMACEUTICALS, INC., et al.,</u></p> <p><u>Plaintiffs,</u> <u>v.,</u></p> <p><u>ZYDUS PHARMACEUTICALS (USA) Inc. and ZYDUS LIFESCIENCES LIMITED,</u></p> <p><u>Defendants.</u></p>		<p><u>Case No.: 1:24-cv-9512- ESK-AMD</u></p>
<p><u>SALIX PHARMACEUTICALS, INC., et al.,</u></p> <p><u>Plaintiffs,</u> <u>v.,</u></p>		<p><u>Case No.: 1:24-cv-7140-ESK- AMD</u></p>

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<u>NORWICH PHARMACEUTICALS, INC., ALVOGEN PB RESEARCH & DEVELOPMENT, LLC, and ALVOGEN, INC.,</u> <u>Defendants</u>	
<u>SALIX PHARMACEUTICALS, INC., et al.,</u> <u>Plaintiffs,</u> <u>v.</u> <u>CIPLA USA, INC. and CIPLA LIMITED,</u> <u>Defendants.</u>	<u>Case No.: 1:24-cv-10213- ESK-AMD</u>
<u>SALIX PHARMACEUTICALS, INC., et al.,</u> <u>Plaintiffs,</u> <u>v.</u> <u>CARNEGIE PHARMACEUTICALS LLC,</u> <u>Defendant.</u>	<u>Case No.: 1:24-cv-10356- ESK-AMD</u>

AGREEMENT TO BE BOUND BY CONFIDENTIALITY ORDER

I, _____, being duly sworn, state that:

~~1.~~ 1. _____ My address is _____.

~~2.~~ 2. _____ My present employer is _____ and the address of my present employment is _____.

~~3.~~ 3. _____ My present occupation or job description is _____.

~~4.~~ 4. I have carefully read and understood the provisions of the Confidentiality Order in this case signed by the Court, and I will comply with all provisions of the Confidentiality Order.

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~~5.~~ 5. I will hold in confidence and not disclose to anyone not qualified under the Confidentiality Order any Confidential or Attorneys' Eyes Only material or any words, summaries, abstracts, or indices of Confidential or Attorneys' Eyes Only material disclosed to me.

~~6.~~ 6. I will limit use of Confidential or Attorneys' Eyes Only material disclosed to me solely for purpose of this action.

~~7.~~ 7. No later than the final conclusion of the case, I will return all Confidential or Attorneys' Eyes Only material and summaries, abstracts, and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to counsel for the party for whom I was employed or retained.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: _____[Name]

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Summary report: Litera Compare for Word 11.10.0.38 Document comparison done on 2/27/2025 12:27:11 PM	
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Delete	76
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<u>Move To</u>	0
<u>Table Insert</u>	10
Table Delete	0
<u>Table moves to</u>	0
Table moves from	0
Embedded Graphics (Visio, ChemDraw, Images etc.)	0
Embedded Excel	0
Format changes	0
Total Changes:	164